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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/026,753	Applicant(s) SHETTY ET AL.	
	Examiner Sheridan R. MacAuley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-18,21-34,37-51 and 53-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-18,21-34,37-51 and 53-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on September 5, 2006.

Claims 1, 2, 6-18, 21-34, 37-51 and 53-61 are pending and examined on the merits.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 48-51 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Antrim et al (U.S. Pat. 5,322,778). The reference discloses a liquefied starch product which appears to be identical to the presently claimed product, based on the fact that the prior art product is a starch liquefact having a DE of 10.05, which is within the range recited in the claims, and a pH of 4.50, within the range recited in the claims, and being produced by an enzyme having essentially the same hydrolytic properties as the enzyme recited in the claims. See, e.g., Antrim at column 7, lines 1-42.

6. It is noted that claim 17 has been amended to recite that the enzyme treatment step must be conducted without the addition of bisulfite, as was claim 1 previously amended. Of the product-by-process claims presently recited, only claims 46 and 47 depend from claims 1 and 17, so this new limitation affects claims 46 and 47 only. However, claims 48-51 do not contain this new limitation. Thus claims 48-51 are still considered to be anticipated by Antrim.

7. It is further noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, the fact remains that the claims

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recite a product made by contacting the same starting material as the prior art, under the same conditions as in the prior art, with the same enzyme as the prior art.

Consequently, even if the process results in the desired product more quickly, the claimed liquefied starch product still appears to be anticipated by the reference.

8. It is noted that the enzyme used to produce the claimed product is from a different species of microorganism than the prior art enzyme. However, even if this results in a nominal difference between the reference product and the claimed product such that there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected nominal differences between starch liquefact products based on normal process variations between different hydrolysis batches and differences in enzyme batches. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding the propriety of this type of alternative rejection, note that MPEP 2113 states that:

... [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP 2113 also clearly states that.

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The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

9. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive of error. It is noted, as argued by applicant, that claim 17 now excludes the use of bisulfite in the enzymatic treatment step. However, only product-by-process claim 47 depends from claim 17. Thus, applicant's argument regarding the new limitation is irrelevant to claims 48-51, because those claims do not contain any limitation excluding the bisulfite used in Antrim.

10. The rejection over Antrim is therefore still properly applied to claims 48-51.

11. Claims 46-51 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Liaw et al (U.S. Pat. 6,136,571).

12. The reference discloses a liquefied starch product which appears to be identical to the presently claimed product, based on the fact that the prior art product is a starch liquefact having a DE of 10-15 which is within the range recited in the claims, and a pH of below 4.50, encompassing the range recited in the claims, and being produced by an enzyme having essentially the same hydrolytic properties as the enzyme recited in the claims. See Liaw at column 1, line 61 to column 2, line 10, disclosing liquefaction to DE of 10-15, followed by adjusting the pH to below 4.5; see also column 15, lines 5-7, disclosing the use of a maltodextrin having a DE of 10 and a pH of 4.5 in the measurement of the half life of a glucoamylase.

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13. It is noted that claim 17 has been amended to recite that the enzyme treatment step must be conducted without the addition of bisulfite. Liaw does not disclose the presence of a bisulfite in the disclosed products. Thus claims 46-51 are considered to be anticipated by Liaw.

14. It is noted that applicant argues that the pH requirement of Liaw results in undesired by-products such as maltulose. Liaw does not disclose the presence of maltulose in the products, and applicant has not presented sufficient, clear and convincing evidence to the contrary. If the pH at which the products were produced did result in the production of undesired by-products, variance in the pH at which the products have been produced would have been a routine matter of optimization, and it would therefore have been obvious for one of ordinary skill in the art to alter the production of the composition taught by Liaw to produce the claimed composition.

15. It is further noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, the fact remains that the claims recite a product made by contacting the same starting material as the prior art, under the same conditions as in the prior art, with the same enzyme as the prior art.

Consequently, even if the process results in the desired product more quickly, the claimed liquefied starch product still appears to be anticipated by the reference.

16. It is noted that the enzyme used to produce the claimed product is from a different species of microorganism than the prior art enzyme. However, even if this results in a nominal difference between the reference product and the claimed product such that there is, in fact, no anticipation, the reference product would, nevertheless,

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have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected nominal differences between starch liquefact products based on normal process variations between different hydrolysis batches and differences in enzyme batches.

17. Thus the claimed invention is either anticipated by, or as a whole was clearly *prima facie* obvious, over the teachings of Liaw, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1, 2, 6-18, 21-34, 37-51 and 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)) in view of JP 10-136979. Claim 1 recites a process for liquefying starch comprising: (a) contacting an aqueous slurry or solution of the starch having a pH between 3.0 and 4.5 with a single addition of a thermostable, acid-stable alpha-amylase obtained by culturing *Bacillus acidocaldarius*, the contacting occurring at an elevated temperature from about 90-155 degrees C without adjusting the pH of the slurry or solution and without the addition of bisulfite, and (b) producing a liquefact having a pH of about 4.0 to 4.5 and DE of about 10-12 within 60-75 minutes of adding the amylase. Claim 2 recites that the contacting of claim 1 occurs without the addition of a calcium salt. Claim 6 recites that the contacting of claim 1 comprises maintaining the elevated temperature for about 5-8 minutes. Claims 7, 8 and 9 recite that the contacting act of claim 1 occurs at 105-110 degrees C, as a single liquefaction step, and wherein at least about 150 ASAA units per gram of the amylase are provided. Claim 10 recites the process of claim 1 wherein, prior to the act of contacting, the slurry or solution is cooked

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at about 140-155 degrees C for about 5-8 seconds and then the temperature of the slurry or solution is reduced to about 90-98 degrees C. Claim 11-13 recite the process of claim 10 wherein the contacting occurs between the amylase and the slurry or solution at about 90-98 degrees C for about 60-90 minutes, as a single liquefaction step, and providing 1.0-10 ASAA units per gram of the amylase. Claims 14-16 recite the process of claim 1 wherein the contacting further comprises a first and second contacting step, the first at about 105-110 degrees C for 5-8 minutes and the second at about 95-98 degrees C, that 10-35 and 1-0 ASAA units per gram of alpha amylase is used in the first and second steps, respectively, and that the first and second steps occur as two liquefaction steps. Claim 17 recites a process for liquefying a starch slurry comprising: (a) providing a thermostable, acid-stable alpha-amylase prepared from *B. acidocaldarius* species; (b) adding the amylase to a starch slurry with a pH of about 3.0-5.0; and (c) heating the mixture to at least 90 degrees C until a starch liquefact having a pH of about 4.0-4.5 and a DE of about 10-12 DE is obtained within 60-75 minutes after adding the amylase, wherein acts (b) and (c) occur without adjusting the pH or adding bisulfite. Claim 18 recies the method of claim 17 wherein steps (b) and (c) occur without the addition of a calcium salt. Claim 21 recites the process of claim 17 wherein step (c) occurs at 90-155 degrees C. Claims 22-25 recite the process of claim 17 wherein step (c) further comprises heating the mixture for about 5-8 minutes to a temperature of between 107-110 degrees C after obtaining DE of 10-12, wherein the mixture is heated to 105-110 degrees C in act (c), wherein step (c) occurs as a single liquefaction step, and wherein step (b) comprises adding at least about 140 ASAA units

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per gram of amylase to the slurry. Claims 26-29 recite the method of claim 17 wherein, prior to step (b) the starch slurry is cooked at about 140-155 degrees C for about 5-8 seconds and then the temperature is reduced to about 90-98 degrees C prior to adding the amylase, step (c) further comprises holding the mixture at about 90-98 degrees C for about 60-90 minutes, step (c) occurs as a single liquefaction step, and step (b) further comprises adding 1.0-5.0 ASAA units per gram of the amylase. Claims 30-32 recite the method of claim 17 wherein step (c) comprises two heating steps, the first at about 105-110 degrees C for 5-8 minutes and the second at about 95-98 degrees C, wherein step (b) further comprises adding about 10-35 ASAA units per gram of the amylase and step (c) further comprises adding 1-10 ASAA units per gram of the amylase, and wherein the first and second heating acts occur as two liquefaction steps. Claim 33 recites a single liquefaction process for starch comprising the same steps recited in claim 17 except that it does not recite that the process is conducted without the addition of bisulfite. Claims 34 and 37-42 recite the same limitations to claim 33 as claims 18 and 21-27 recite for claim 17. Claim 43 recites a starch liquefaction method comprising: (a) providing a starch slurry with a pH between 3.0 and 4.5 and a thermostable, acid stable alpha amylase capable of hydrolyzing starch at a pH as low as 3.0 from *B. acidocaldarius*; (b) mixing the starch slurry and about 150 ASAA units per gram of the amylase without adjusting the pH of the slurry; (c) maintaining the mixture of step (b) at 95 degrees C for about 90-120 minutes; and (d) jet-cooking the mixture resulting from step (c) for about 5-8 minutes at about 105-110 degrees C to obtain a liquefact having a DE of approximately 10-12 within 60-75 minutes after mixing the

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amylase. Claim 44 recites a starch liquefaction method comprising: (a) providing a starch slurry with a pH between 3.0 and 4.5; (b) jet-cooking slurry for about 5-8 seconds at about 140-155 degrees C without adjusting the pH of the slurry; (c) lowering the temperature of the cooked slurry from step (b) to about 95-98 degrees C and adding about 1.0 to 5.0 ASAA units per gram of the amylase; and (d) allowing the mixture to undergo hydrolysis for about 60-90 minutes to produce a liquefact having a DE of approximately 10-12 within 60-75 minutes after mixing the amylase. Claim 45 recites a starch liquefaction method comprising the steps of (a) providing a starch slurry having a pH between 3.0 and 4.5 and the amylase as recited in claim 43; (b) mixing the starch slurry and about 10-30 ASAA units per gram of the amylase without adjusting the pH of the slurry; (c) jet cooking the mixture resulting from step (b) for about 5 minutes; (d) adding about 1-5 ASAA units per gram of the amylase; (e) continuing liquefaction at about 95-98 degrees C for as little as 30-90 minutes to obtain a liquefact having a DE of approximately 10-12 within 60-75 minutes after adding the amylase; and (f) jet cooking the mixture resulting from step (e) for about 1-2 minutes. Claims 46-49 recite a starch liquefact made by the processes of claims 1, 17, 33 and 43, respectively, the liquefact characterized as having a pH of about 4.0-4.5, free of maltulose, and suitable for saccharification without inactivation of the amylase and without adjustment of the about 4.0 to 4.5 pH of the liquefact. Claims 50 and 51 recite a starch liquefact made by the processes of claims 43 and 44, respectively, the liquefact characterized as having a pH of about 4.0-4.5, free of maltulose, and suitable for saccharification following the thermal inactivation of the amylase and without adjustment of the about 4.0 to 4.5 pH of the

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liquefact. Claim 53 recites a process for producing glucose from starch comprising: (a) providing a starch slurry having a pH between 3.0 and 4.5; (b) adding a thermostable, acid-stable alpha-amylase capable of hydrolyzing starch at a pH between 3.0 and 4.5, the amylase cultured from *B. acidocaldarius*; (c) liquefying the starch slurry by heating the mixture until a DE of about 10-12 is reached within 60-90 minutes after the addition of the amylase without the production of maltulose; and (d) adding a saccharification enzyme to the liquefied starch slurry from step (c) and maintaining a resulting saccharification mixture at about 60 degrees C for between about 10-48 hours or until about 95% glucose yield is achieved. Claims 54-61 recite the method of claim 53 wherein step (a) is carried out without adjusting the pH of the starch slurry and without the addition of calcium salt, step (b) further comprises heating the mixture at about 105-110 degrees C for 5-8 minutes, act (c) is carried out without inactivating the amylase and without adjusting the pH of the slurry, and further comprises adding glucoamylase, or a mixture of glucoamylase and pullulanase, to the starch slurry, and wherein the pH of the process is between about 4.0 and 4.5.

22. Shetty discloses a process of preparing glucose from starch, said process using the claimed process parameters. See, e.g. pages 6 and 14. Note in particular the disclosure on page 6 of the desirability of a liquefact having a DE of 10 to 12. Shetty differs from the claims in that Shetty uses a different α -amylase enzyme than that recited in the claims. However, Shetty discloses that α -amylases active at acidic pH are advantageous in processes of producing glucose from starch. Specifically, the liquefaction step is improved by decreasing chemical demand for pH adjustment,

reducing color and by-product formation, and lowering refining requirements and costs (Shetty, page 7). Also, the lower pH afforded by the use of acidophilic α -amylase eliminates the undesirable formation of maltulose (Shetty, page 8). Shetty also discloses that enzymes that do not require calcium for stability are advantageous, as are relatively thermostable enzymes. Shetty, page 11, last sentence. ("It is evident from the above data that an improved thermostable alpha-amylase which can operate at a pH below 6.0 and at lower or no calcium will significantly reduce refining costs and improve the final glucose yield.")

23. As is evident from the English translation, JP '979 discloses an α -amylase which meets exactly the criteria disclosed by Shetty as being desirable and advantageous for use in the disclosed process of preparing glucose from starch. Specifically, the enzyme is thermostable, acid-stable, optimally active at a pH of about 4, and does not require calcium for activity (see Table 2). Thus, the artisan of ordinary skill practicing Shetty's process clearly would have recognized that the enzyme disclosed by JP '979 possesses all the properties required for use in Shetty's process. The artisan of ordinary skill would therefore clearly have been motivated to use the enzyme of JP '979 in Shetty's process. A holding of obviousness is therefore required.

24. Because it is not clear that the enzyme units used in JP '979 correspond to the units used in applicant's claims, it is not clear that either reference discloses the use of the claimed amount of amylase. However, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that the rate of the liquefaction would have been readily optimized, depending on the amount of enzyme used. Thus,

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the claimed amounts of enzyme must be considered obvious in view of the fact that enzyme concentration was known to be a result-effective parameter, and therefore routinely optimized by artisan of ordinary at the time of applicant's invention.

25. It is again noted that the claims require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, it is respectfully submitted that this limitation does not serve to distinguish the claims from the cited prior art.

Specifically, it is noted that at 75 minutes the DE of the various liquefaction processes disclosed by Shetty is about 9, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12." See page 14 of Shetty, especially figs. 2 and 3.

Moreover, the speed of an enzymatic reaction can be increased simply by increasing the ratio of enzyme to substrate, that is, by increasing the amount of enzyme or decreasing the amount of substrate. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill would have had a reasonable expectation that the claimed DE could be reached in the claimed amount of time by following the teachings of Shetty and JP '979. A holding of obviousness is therefore required.

26. All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant urges that Shetty fails to provide a reasonable expectation of success, at best providing making the claimed processes "obvious to try." However, Shetty discloses the desirability in starch liquefaction processes of using an enzyme having the exact properties of the enzyme described by JP '979. Contrary to applicant's argument, Shetty does in fact state how the process should be conducted by saying that an enzyme capable of liquefaction at acidic pH

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should employed in a liquefaction conducted at acidic pH. Respectfully, the clarity of Shetty's disclosure, combined with that of JP '979, goes well beyond "obvious to try."

27. Regarding Shetty's two-stage liquefaction being different than that claimed by applicant, note specifically that applicant's claims recite the process in "open" comprising language, which encompasses any additional steps, including those present in the Shetty process. Moreover, the liquefaction shown on page 5 is not the only liquefaction process disclosed by Shetty. The liquefaction processes graphically depicted on page 14 of Shetty all have a single addition of enzyme resulting in the claimed DE values, thus meeting this limitation in applicant's claims.

28. Moreover, applicant is in error by suggesting that all of the claims require a single addition of enzyme. In fact, only claims 1, 2, 6-16 recite a "single addition" of enzyme, and claims 33, 34 and 37-42 recite a "single liquefaction step process for starch." This leaves process claims 17, 18, 21-32, 43-45 and 53-61, which do not recite such a limitation, contrary to applicant's argument. Thus, applicant's argument regarding a single step process is irrelevant to process claims 17, 18, 21-32, 43-45 and 53-61, as well as being irrelevant to product-by-process claims 46-51. As to claims 1, 2, 6-16, 33, 34 and 37-42, it is again noted that those processes are recited in open "comprising" language, which does not exclude process steps not mentioned by the claims. If applicant considers the claims to recite a process "consisting" of a single addition of enzyme, then the claims should so state.

29. As to whether a DE of 10-12 can be reached at the claimed pH in the claimed amount of time, as applicant is surely aware, it is textbook knowledge that the speed of

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an enzyme reaction can be increased (up to V_{\max}) by increasing the ratio of enzyme to substrate. Thus, the rejection of record being an obviousness rejection rather than an anticipation rejection, the artisan of ordinary skill, recognizing the fact that the rate of an enzyme reaction could be increased by increasing the ratio of enzyme to substrate, clearly would have been motivated to have used that technique to increase, or at least optimize, the rate of the reaction described by Shetty. At the very least, in view of the fact that the majority of the claims do not recite any limitation with respect to enzyme amount, applicant is incorrect in arguing that the claims recite any result unexpected from the cited prior art with respect to reaction rate. Moreover, with respect to those claims reciting enzyme amounts, a number of those claims (e.g. claim 9) recite only minimum amounts, therefore encompassing very large amounts of enzyme that would in fact be expected to generate fast enzyme reaction rates. Further still, with respect to those claims reciting maximum enzyme amounts (e.g. claim 13), there is nothing on the record indicating that the claimed enzyme behaves in any manner unexpected from the disclosures of the cited prior art.

30. With respect to the disclosure in JP '979 of adjusting the pH before adding enzyme, supposedly being different from the claims under examination, it is respectfully pointed out that only claims 54 and 56 specifically exclude pH adjustment before enzyme addition. The rest of the pending process claims only exclude pH adjustment during the contacting step. Thus, applicant's argument about this limitation is irrelevant to all but two pending claims. With respect to those claims, as has been pointed out previously, if one were to use the enzyme disclosed by JP '979 in Shetty's process, one

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would not have to adjust the pH to an acidic one, since the pH was already at that level. Specifically, Shetty clearly discloses that refined starch from the wet milling of grain enters the liquefaction process at pH 4.0 to 5.0. See Shetty at page 7. Shetty also discloses that liquefaction at that pH range would be advantageous because it would reduce the chemical demand for pH adjusting agents. See, *id.* Thus, by using the JP '979 enzyme in the liquefaction process of Shetty, one would not need to adjust the pH. Avoidance of the pH adjustment step is clearly described by Shetty as being advantageous. Moreover, the artisan of ordinary skill would have been motivated to have used the JP '979 enzyme in Shetty's pH 4.0 to 5.0 liquefaction process, since Shetty's preferred pH range is the exact pH optimum of the JP '979 enzyme. Moreover, as discussed above, the single enzyme addition is disclosed at least by Shetty. Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

31. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

32. Applicant's arguments filed September 9, 2006 have been fully considered but they are not persuasive. Applicant argues that the rejection of claims 48-51 under 35

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USC 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as obvious over Antrim has been overcome by applicant's amendment to claim 17.

Applicant argues that Liaw does not anticipate or render obvious the products recited in claims 46-51. Applicant argues that Shetty does not provide a reasonable expectation of success in performing the invention taught by the prior art, that Shetty teaches away from the presently claimed pH conditions, and that neither Shetty nor JP '979 teach the single addition of an amylase and that neither reference suggests that the performance of the method at the claimed pH would result in the claimed DE.

33. In response to applicant's argument that the rejection of claims 48-51 under 35 USC 102/103 over Antrim has been overcome by applicant's amendment to claim 17, it is noted that only product-by-process claim 47 depends from claim 17. Therefore, claims 48-51 stand rejected under 35 USC 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as obvious over Antrim.

34. In response to applicant's argument that Liaw does not anticipate or render obvious the product-by-process claims 46-51 because the pH requirement of Liaw results in undesired by-products such as maltulose, Liaw does not disclose the presence of maltulose in the products, and applicant has not presented sufficient, clear and convincing evidence to the contrary. If the pH at which the products were produced did result in the production of undesired by-products, variance in the pH at which the products have been produced would have been a routine matter of optimization, and it would therefore have been obvious for one of ordinary skill in the art to alter the production of the composition taught by Liaw to produce the claimed composition.

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35. In response to applicant's arguments that Shetty does not provide a reasonable expectation of success in performing the invention taught by the prior art, it is noted that Shetty discloses the desirability in starch liquefaction processes of using an enzyme having the exact properties of the enzyme described by JP '979. Contrary to applicant's argument, Shetty does in fact state how the process should be conducted by saying that an enzyme capable of liquefaction at acidic pH should be employed in a liquefaction conducted at acidic pH. Further, it is noted that, at the time of the invention, there had been a recognized need in the art for liquefaction at an acidic pH, as taught by Shetty. There were a finite number of potential solutions, one of which was the use of the enzyme disclosed by JP '979. One of ordinary skill in the art could have pursued this solution with a reasonable expectation of success, as taught by Shetty, who discusses that the process performed at a lower pH would be both successful and beneficial (see p. 7). Therefore, as applicant has stated, the claimed invention would in the very least have been "obvious to try". However, as it has been stated, the teachings, suggestion and motivation to combine the references are provided in the prior art.

36. In response to applicant's argument that Shetty teaches away from the presently claimed pH conditions, it is noted that Shetty discusses that performing the process at the claimed pH would be beneficial (see p. 7). Applicant is therefore in error by suggesting that Shetty teaches away from the claimed pH conditions.

37. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the single addition of an amylase in the claimed process) are not recited in the

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rejected claim(s). Applicant's claim language is open to additional steps in the claimed process because the claims recite processes "comprising" the claimed steps. If applicant wishes to recite a process "consisting" of the single addition of an enzyme, then the claims should be thus amended. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

38. In response to applicant's argument that neither Shetty nor JP '979 suggest that the performance of the method at the claimed pH would result in the claimed DE, it is noted that that increasing the speed of an enzymatic reaction (up to V_{max}) can be achieved by increasing the ratio of enzyme to substrate. Therefore, even if the combined references would not achieve the claimed DE, it would have been a matter of routine optimization to adjust the ratios of the components of the reaction to arrive at the claimed invention. One would have been motivated to achieve a DE of 10-12 because this value is taught by Shetty (see p. 6). Thus, the claimed method would have been obvious in view of the combined teachings.

39. Therefore, applicant's arguments have been fully considered, but have not been found persuasive.

Conclusion

40. No claims are allowed.

41. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651